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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SIGLER, JAY R

ART UNIT

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,509	Applicant(s) CLEMENT ET AL.	
	Examiner JAY R. SIGLER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 6-21 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

Additionally, claim 1 recites the limitation "the connecting part" in line 9. There is insufficient antecedent basis for this limitation in the claim. Claim 12 recites the limitation "each connecting linking rod" in line 8. There is insufficient antecedent basis for this limitation in the claim. Applicant is asked to review and amend the claims so that the language used to claim certain structures is consistent in the independent claims and their dependent claims.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 7, lines 3-6, applicant positively recites part of a human, i.e. "said bearing surface... is a surface provided on... the vertebral bone itself". Thus, claim 7 includes a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 6-9, 11-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,554,831 to Rivard et al. (hereinafter "Rivard") in view of US 5,380,325 to Lahille et al. (hereinafter "Lahille") and US 5,254,118 to Mirkovic (hereinafter "Mirkovic").

a. Concerning claims 1, 2, 12 and 16, Rivard discloses vertebral osteosynthesis equipment, including bony anchoring members, two linking rods (12 and 14), intended to be connected to these anchoring members, and parts (16a and 16b) for connecting these rods to these anchoring members; at least one of the anchoring members is of the "polyaxial" type (embodied by the ball

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joint shown in Fig. 2, col. 4, ll. 11-16) comprising a proximal stud (30) articulated with respect to a base portion (upper part of 20) enabling bony anchoring; clamping means (40) enable assembly of the connecting part on the anchoring member; wherein the proximal stud comprises a surface (36) forming an axial stop, against which the connecting part to be installed on the polyaxial anchoring member is intended for resting (shown in Fig. 2), and in that said clamping means enable to clamp this connecting part against this surface, said surface being positioned so that the connecting part, when it is clamped against this surface, is not clamped against the base portion so that there remains, after clamping, a possibility of articulated backlash of the proximal stud with respect to said base portion (embodied by Fig. 2, col. 4, ll.25-30).

Rivard does not specifically disclose including an elastically deformable structure. Lahille suggests vertebral osteosynthesis equipment including an elastically deformable structure 25 interposed between a connecting part 3 and a bearing surface 23 in order to dampen and thus cancel damaging movements to the rod or screws that could cause cracks or breaks (col. 5, l. 68 to col. 6, l. 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to include an elastically deformable structure, such as suggested by Lahille, in the invention of Rivard in order to dampen and thus cancel damaging movements to the rod or screws that could cause cracks or breaks.

Rivard , in view of Lahille, does but does not specifically suggest that the axial stop and the proximal stud are formed to enable the adjustment of the axial

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position of the axial stop with respect to the proximal stud. It would naturally follow that this would in turn adjust the axial position of the connecting member with respect to proximal stud. Mirkovic suggests vertebral osteosynthesis equipment where the axial position of the connecting member 30 is adjustable on the proximal stud (embodied by top part of 14) and this is done using an axial stop (embodied by nut 38) which is also adjustable in order to position the rod properly (embodied by the Abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to use an adjustable axial stop, such as suggested by Mirkovic, in the modified invention of Rivard, in view of Lahille, in order to position the rod properly. Additionally, the claim is unpatentable because it has been held that adjustability, where needed, is not a patentable advance, and because there was an art-recognized need for adjustment. *In re Stevens* , 212 F.2d 197, 101 USPQ 284 (CCPA 1954). Concerning the further limitation, an adjustable axial stop would be capable of clamping the elastically deformable structure to the bearing surface.

b. Concerning claims 3 and 13, the elastically deformable structure of Lahille is a compressible material and would dampen movement over the whole backlash of the stud considering it encircles the stud.

c. Concerning claims 4 and 14, the claim is unpatentable because it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

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experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

d. Concerning claims 6 and 15, the proximal stud of Rivard is threaded and adding a tapered hole to allow for an easier application of the axial stop onto the proximal stud would have been an obvious improvement in the art.

e. Concerning claim 7, Lahille suggests the elastically deformable structure resting on the bearing surface.

f. Concerning claim 8, 17, 20, and 21, Rivard, in view of Lahille and Mirkovic, suggests the claimed invention except for the implant including a ceramic or titanium nitride coating layer. However, ceramic or titanium nitride coating layers were art recognized for providing a smooth and resistant coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include ceramic or titanium nitride coating layers, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

g. Concerning claim 9 and 18, Rivard, in view of Lahille and Mirkovic, suggests the articulation of the proximal stud consists of spherical faces (46 and opposite face), but does not specifically teach that the diameter of the faces is double the diameter of the stud. The claim is unpatentable because it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the

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claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984).

h. Concerning claim 11, the connecting part of Rivard comprises a rounded section 23 and two parallel drilled wings (24 and 26).

6. Claims 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivard, in view of Lahille and Mirkovic, as applied to claim 12 above (see also Point 5(h) above), and further in view of WO 03/007828 to Fortin et al. (hereinafter "Fortin"). US 2005/0165396 is the national stage application of WO 03/007828 and is being relied on as a translation. The following references are drawn to US 2005/0165396.

Rivard, in view of Lahille and Mirkovic, suggests the claimed invention except for the special structure of the rod. Fortin discloses a rod for use in vertebral osteosynthesis equipment that includes a portion with elastically deformable structure 122 and articulated stud 110, another portion of rod 16 including a bearing zone 114, and a clamping means 112 to allow the rod to provide both resistance and mechanical stress damping forces with the purpose of compensating for any deficiency in the flexibility of certain anatomical links of the human body. It would have been obvious to someone of ordinary skill in the art at the time of the invention to include the rod of Fortin in the modified invention of Rivard, in view of Lahille and Mirkovic, in order to allow the rod to provide both resistance and mechanical stress damping forces with the

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purpose of compensating for any deficiency in the flexibility of certain anatomical links of the human body.

Response to Arguments

7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. In response to applicant's argument that the structure "allows a specific function[:]. . . allowing to adjust, in function of the tightening of the dampening part, the dampening effect produced by this dampening part, in order to adapt the dampening obtained to the characteristics of the patient (weight, age, affection to be treated~ etc)" (see page 13 of previous reply), the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733